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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/829,426 | 04/21/2004 | Jonah Shacknai | 01-40175-US-P2-D-C | 8788 |

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| EXAMINER | |
|---|---|
| VENKAT, JYOTHSNA A | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1615 | |

DATE MAILED: 09/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/829,426 | SHACKNAI ET AL. | |
| | Examiner | Art Unit | |
| | JYOTHSNA A VENKAT Ph. D | 1615 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *21 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *63,65-67,70,71 and 77-80* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *63,65-67,70,71 and 77-80* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/21/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

Receipt is acknowledged of preliminary amendment and IDS filed on 4/21/04 and 7/21/04. The preliminary amendment canceled claims 1-62, 64, 72-76 and 81. The preliminary amendment after claims 68-69 does not have the word canceled. But the remarks section specifically explains that claims 68-69 are canceled. In response to this office action applicants are requested to address all the claims. Claims 63, 65-67, 70-71 and 77-80 are pending in the application, the status of the application is as follows:

### *Claim Rejections - 35 USC § 112*

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

**2.** Claims 63, 65-67, 70-71 and 77-80 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a written description rejection.**

To satisfy the Written description requirement, applicant must convey with reasonable clarity to one skilled in the art, as of the filing date that applicant were in possession of the claimed invention. Applicant's claims are drawn to "*A method for enhancing absorption of sulfur in skin comprising*

*Applying a composition, wherein the composition comprises one or more high sorption bases, sulfur and one or more sulfur derivative, wherein the sulfur derivative comprises one or more*

*compounds selected from the group consisting of organic sulfides, inorganic sulfides, organic mercaptans, inorganic mercaptans, cationic sulfur compounds, H2S, sulfuric acid, bisulfides, sulfur dioxide, thiols and sodium sulfacetamide and wherein the high sorption base comprises one or more compounds selected from the group consisting of non-swelling clay and silicon; and Absorbing sulfur in the skin, wherein the skin comprises one or more selected from the group consisting of epidermis, dermis, and stratum corneum.*

The specification at page 2, paragraphs 6-9 define the derivatives of sulfur as selenium sulfides, potassium sulfides. These two compounds belong to the class of inorganic sulfides claimed in claim 11. The specification then describes poly-potassium sulfide, poly- calcium sulfide and then describes the compounds like thiols, organic salts and organic sulfides where R is an organic compound and its salt that can bind ionically or covalently to sulfur. The two compounds described are sodium mercaptoacetic acid . This corresponds to R being acetyl group linked covalently to sulfur and the other valence is attached to sodium atom. The next compound described is glutathione, which is a tripeptide. The instant application fails to describe the nature of R. Organic by definition includes various groups. It can be unsubstituted or substituted alkyl, alkenyl, aryl, acyl, and heterocyclic. Thus the group R can include very different moieties like large peptides to the small organic molecules like monocyclic heterocyclic compounds to the simple thioglycolic acid. The same is true for Sulfites, and metabisulfites. The expression sulfur derivatives, does not meet the written description requirement because one of ordinary skill in the art could not recognize or understand the compounds form mere recitation of R being organic radical in the organic sulfide category and to the nature of inorganic in inorganic sulfites, metabisulfites. Claims employing sulfur derivatives at the point of novelty, such as applicants',

neither provide guidance as to the nature R that is required to practice the inventions, nor "inform the public" during the life of the patent of the limits of the monopoly asserted. Applicants claimed expression represents only an invitation to experiment regarding possible compounds suitable as sulfur derivatives, which can be used in the compositions for absorbing irritants in the skin and delivering sulfur.

3. Claims 63, 65-67, 70-71 and 77-80 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant application is claiming *a method for enhancing absorption of sulfur in skin comprising*

*Applying a composition, wherein the composition comprises one or more high sorption bases, sulfur and one or more sulfur derivative, wherein the sulfur derivative comprises one or more compounds selected from the group consisting of organic sulfides, inorganic sulfides, organic mercaptans, inorganic mercaptans, cationic sulfur compounds, H2S, sulfuric acid, bisulfides, sulfur dioxide, thiols and sodium sulfacetamide and wherein the high sorption base comprises one or more compounds selected from the group consisting of non-swelling clay and silicon; and Absorbing sulfur in the skin, wherein the skin comprises one or more selected from the group consisting of epidermis, dermis, and stratum corneum.*

The instant application is claiming method-using sulfur. Applicant's attention is drawn to "Maibach et al., in the Journal of American Academy of Dermatology pp, 154-155(1990).The article clearly teaches that using 6% sulfur in the base petrolatum is effective and higher

concentration of sulfur is toxic. Based upon the above fact, it is the examiner position that only specific concentration of sulfur can be used for the claimed method without causing toxicity, and any concentration cannot be used for the claimed method. See *In re Marzocchi* 169, USPQ 367.

4. Claims 63, 65-67, 70-71 and 77-80 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for using the claimed method using the compositions which has sulfur and sodium sulfacetamide, does not reasonably provide enablement for claimed method using sulfur and sulfur derivatives. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is " *undue* ". See ***In re Wands, 858 F.2d 731, 737, 8 USPQ 2d 1400, 1404 (Fed. Cir. 1998).*** The court set forth the eight factors to consider when assessing if a disclosure would require undue experimentation. Citing *Ex parte Forman, 230 USPQ 546*, the court recited eight factors

These factors include, but are not limited to:

1*) The breadth of the claims,*

*2) The nature of the invention,*

*3) The state of the prior art,*

*4) The level of one of ordinary skill,*

*5) The level of predictability in the art,*

*6) The amount of direction provided by the inventor,*

*7) The existence of working examples*

*8) The quantity of experimentation needed to male or use the invention based on the content of the disclosure.*

(1 and 2) The breadth of the claims and the nature of the invention: The claims are drawn to *a method for enhancing absorption of sulfur in skin comprising*

*Applying a composition, wherein the composition comprises one or more high sorption bases, sulfur and one or more sulfur derivative, wherein the sulfur derivative comprises one or more compounds selected from the group consisting of organic sulfides, inorganic sulfides, organic mercaptans, inorganic mercaptans, cationic sulfur compounds, H2S, sulfuric acid, bisulfides, sulfur dioxide, thiols and sodium sulfacetamide and wherein the high sorption base comprises one or more compounds selected from the group consisting of non-swelling clay and silicon; and Absorbing sulfur in the skin, wherein the skin comprises one or more selected from the group consisting of epidermis, dermis, and stratum corneum.*

3. The state of the prior art: *The art cited above by Maibach et al. ,clearly teaches that sulfur at certain concentration causes toxicity. Applicant's attention is drawn to col.2, page 155, where the article teaches that infant treated with 10% sulfur had illness and at the last paragraph Maichbach et al., state that 6% sulfur is not toxic.*

(6-7) The amount of direction provided by the inventors and the existence of working examples: *Applicants have provided at page 12 of specification data with respect to the four formulations A, B, C and D. All the four formulations use sulfur and sodium sulfacetamide as the sulfur derivative for the claimed method. The specification describes various compounds for the sulfur derivatives. See the written description rejection. The specification fails to describe the*

*nature R for the organic sulfide and nature of R for the sulfites and inorganic sulfites. None of the sulfur derivatives are art-recognized equivalents. They are drawn to divergent compounds.*

(8) The quantity of experimentation needed to make or use the invention bases on the content of the disclosure: *The instant specification gives no indication to one skilled in the art, that one could use the combination of sulfur( any concentration) with different sulfur derivatives( which lack written description),which are divergent in nature and have a reasonable expectation of success. Due to the divergent nature of the sulfur derivatives and since applicants are not in possession of the subject matter drawn to all these divergent compounds and due to scientific journal which clearly teaches that only particular concentration of sulfur can be used without any toxicity, it is the position of the examiner that one of ordinary skill in the art cannot extrapolate the test results to all the sulfur derivatives, and the practice of the full scope of the invention would require undue experimentation.*

5. Claims 63, 65-67, 70-71 and 77-80 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The following reasons apply:

I. The recitation of " comprises one or more of the group consisting of " for defining the Markush group is indefinite. The claims are unclear as to applicant's intent (claims 63 and 77).

II. Claims 70 and 78 are unclear as to applicant's intent. The claims recite " comprises" followed by one compound. The claim would read better by amending " comprises " to " is".

***Double Patenting***

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 63, 65-67, 70-71 and 77-80 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of U. S. Patent 6,787, 160 B2 ('160). An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ 2d 1226(Fed. Cir. 1998); *In re Goodman*, 11 F. 3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F. 2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentable distinct from each other because claim 63 is generic to all that is recited in claim 1 of patent. That is claim 1 of patent falls entirely within the scope of claim 63, or in other words, claim 63 is antiicpated by claim 1 of patent.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JYOTHSNA A VENKAT Ph. D whose telephone number is 571-272-0607. The examiner can normally be reached on Monday-Thursday, 9:30-7:30:1st and 2nd Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, THURMAN K PAGE can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JYOTHSNA A VENKAT Ph. D
Primary Examiner
Art Unit 1615

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